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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/684,008	10/06/2000	Timothy A.M. Chuter	ENDOV-54176	9810

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FULWIDER PATTON LEE & UTECHT, LLP  
HOWARD HUGHES CENTER  
6060 CENTER DRIVE  
TENTH FLOOR  
LOS ANGELES, CA 90045

EXAMINER

CHATTOPADHYAY, URMI

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 05/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/684,008

Applicant(s)

CHUTER, TIMOTHY A.M.

Examiner

Urmi Chattopadhyay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 February 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3,7 and 11-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,7 and 11-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 October 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Response to Amendment*

1. The amendment filed 2/27/03 has been entered as Paper No. 10. Claims 1, 3, and 7 have been amended, claims 2, 4, 5, 6 and 8-10 have been canceled, and claims 11-20 have been added. The claims being considered for further examination on the merits are 1, 3, 7 and 11-20.

### *Oath/Declaration*

2. The Declaration and Power of Attorney filed 2/28/03 has been entered as Paper No. 11.

3. The oath or declaration is still defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required.

See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:  
It does not say that the inventor is a sole inventor.

The MPEP clearly states the following in 602:

#### SOLE OR JOINT DESIGNATION

In the oath, the jurat must be filled out, and the word "sole" or "only" must appear if there is but one inventor, and "joint" if two or more inventors.

When joint inventors execute separate oaths or declarations, each oath or declaration should make reference to the fact that the affiant is a joint inventor together with each of the other inventors indicating them by name. This may be done by stating that he or she does verily believe himself or herself to be the original, first and joint inventor together with "A" or "A & B, etc." as the facts may be.

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Form paragraphs 6.05 and 6.05.04 may be used to notify applicant that the oath or declaration is defective because the sole or joint designation has been omitted.

***Claim Objections***

4. Claim 7 is objected to because of the following informalities:

- ✓ a. Claim 7, line 2, "an" should be changed to --a-- after "with".
- ✓ b. Claim 16, line 2, it appears that "stent" should be changed to --step--.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 17 requires the main body to lack self-expanding structure attached thereto prior to placement within the vasculature. The specification does not preclude the inclusion of a self-expanding structure attached to the main body prior to placement within the vasculature, and therefore, constitutes new matter.

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7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 7 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 1 is indefinite because it is not possible for the at least one attachment system to be compressible between the two conditions of compressed and expanded. Examiner suggests rewording the clause as --and the at least one attachment system being compressible and expandable radially between an expanded and compressed condition-- or --and the at least one attachment system being compressible radially from an expanded condition to a compressed condition--.

9. Claim 1 recites the limitation "the bore" in line 15. There is insufficient antecedent basis for this limitation in the claim.

10. Claim 1 is indefinite because the last clause requires implantation of the attachment system in the graft, while the step preceding it already includes positioning the at least one attachment system within the graft and activating the at least one attachment system. It appears the last clause should be a "wherein" clause, further limiting the activating step to forming a seal between the graft and the vascular wall.

11. Claim 7 is indefinite because it is dependent on claim 5, which was canceled by the amendment. It appears the claim should be dependent on claim 1 or claim 3.

✓ 12. Claim 7 is indefinite because it is unclear which "inferior end" on line 9 the first end of the third catheter is connected to. It appears that "inferior end" should be changed to --inferior end of the second leg--.

***Claim Rejections - 35 USC § 102***

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 11-13 and 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Orth (USPN 5,800,521 as cited in applicant's IDS).

Orth discloses a method for aneurysm repair with all the elements of claim 11. See Figures 1-4 and columns 1-2, lines 64-45 for a method of implanting a modular graft device within vasculature, the modular graft device including a bifurcated main body (Figure 4) having a first end portion and a second end portion including a first leg and a second leg. The bifurcated main body is inserted within vasculature and a traction force is applied to the first end of the main body (see column 2, lines 5-9 for draw strings applying a traction force to the distal end of the graft). See Figure 4 for inserting a radially self-expanding (column 4, lines 28-30) device within one of the first and second legs.

Claim 12, see column 4, lines 11-16 for inserting radially self-expanding device within each of the first and second legs.

Claim 13, see Figure 3 for radially self-expanding device inserted within first end portion of the bifurcated graft.

Claim 17, see Figure 4 for the main body lacking self-expanding structure attached thereto prior to placement within vasculature.

Claim 18, see abstract for main body being a graft.

Claim 19, see column 2, lines 1-5 for main body placement by direct percutaneous insertion.

Claim 20, see column 4, lines 8-24 for attachment system placement by direct percutaneous insertion.

***Claim Rejections - 35 USC § 103***

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orth in view of Inoue (USPN 5,843,162).

Orth discloses a method for aneurysm repair with all the elements of claim 11, including applying a traction force to the first end, but is silent to applying a traction force on the first and second legs, as required by claims 14-16. Inoue discloses a method of implanting a modular bifurcated graft device within vasculature, wherein positioning the main body adjacent a diseased portion of vasculature includes applying a traction force to the first and second legs of

the bifurcated main body in order to position the legs into each of the bifurcated branches of the blood vessel. See Figures 40-42 and column 21, lines 5-13. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Inoue to modify the method of Orth by including the step of applying a traction force to the first and second legs of the bifurcated main body in order to properly position the legs into each of the bifurcated branches of the blood vessel prior in inserting the branch anchors.

*Allowable Subject Matter*

17. Claim 1 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.
18. Claims 3 and 7 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

*Conclusion*

19. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

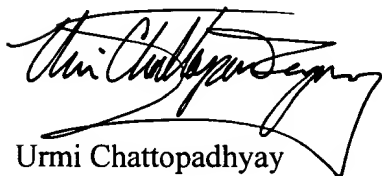


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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

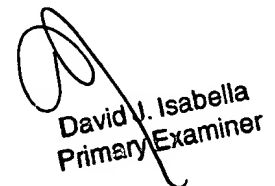
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 305-3590. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.



Urmi Chattopadhyay

Art Unit 3738



David J. Isabella  
Primary Examiner

uc

May 14, 2003